

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

GREGORY W. BARAN, M.D.,)	Civil Action No.: 1:04CV1251
)	
Plaintiff,)	Judge O'Malley
)	
vs.)	Mag. Judge Baughman
)	
)	
MEDICAL DEVICE TECHNOLOGIES, INC.)	
ET AL.)	
)	
Defendants.)	
)	
)	
_____)	

**PLAINTIFF GREGORY W. BARAN, M.D.'S CORRECTED OPPOSITION TO
DEFENDANT MEDICAL DEVICE TECHNOLOGIES, INC.'S MOTION FOR
SUMMARY JUDGMENT OF NONINFRINGEMENT**

TABLE OF CONTENTS

I. INTRODUCTION AND SUMMARY OF THE ARGUMENT	1
II. FACTUAL BACKGROUND.....	2
A. THE PARTIES.....	2
B. THE ACCUSED PRODUCTS	3
1. Key Components of the Accused Products.....	3
2. Undisputed Operation of the Accused Products	5
3. Disputed Operation of the Accused Products	7
C. THE DISPUTED LIMITATIONS AND THEIR CONSTRUCTION	10
III. LEGAL STANDARDS	13
A. LEGAL STANDARDS FOR SUMMARY JUDGMENT	13
B. LEGAL STANDARD FOR LITERAL INFRINGEMENT	13
IV. ARGUMENT	14
A. THE ACCUSED PRODUCTS INCLUDE A MANUALLY OPERABLE CHARGING MEMBER FOR MOVING THE GUIDE TO THE CHARGED POSITION AGAINST THE URGING OF THE COIL SPRING	14
B. THE ACCUSED PRODUCTS INCLUDE A CANNULA MOUNT AFFIXING THE CANNULA TO THE GUIDE.....	18
C. THE ACCUSED PRODUCTS INCLUDE A RELEASE MEANS FOR RETAINING THE GUIDE IN THE CHARGED POSITION	21
1. The Release Means for Retaining in the Accused Products Perform the Identical Function as in the Claimed Invention	23
2. The Release Means for Retaining in the Accused Products Operate in Substantially the Same Way as in the Claimed Invention	24
3. The Release Means for Retaining in the Accused Products Produce Substantially the Same Result as in the Claimed Invention	26
4. Dr. Baran Does not Advocate an Improper Use of the Accused Products	27
V. CONCLUSION.....	30

TABLE OF AUTHORITIES

CASES

<i>Adickes v. S. H. Kress & Co.</i> , 398 U.S. 144 (1970).....	13
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986).....	13
<i>Applied Med. Res. Corp. v. U.S. Surgical Corp.</i> , 448 F.3d 1324 (Fed. Cir. 2006).....	23
<i>BMC Resources, Inc. v. Paymentech, L.P.</i> , 498 F.3d 1373 (Fed. Cir. 2007).....	13
<i>Canon Computer Sys., Inc. v. Nu-Kote Int’l Inc.</i> , 134 F.3d 1085 (Fed. Cir. 1998).....	24
<i>Celotex Corp. v. Catrett</i> , 477 U.S. 317 (1986).....	13
<i>Ekstam v. Ekstam</i> , 2007 WL 2571968 (E.D. Mo. 2007).....	1
<i>In re Gabapentin Patent Litigation</i> , 503 F.3d 1254 (Fed. Cir. 2007).....	14
<i>Intel Corp. v. U.S. Intern. Trade Com’n</i> , 946 F.2d 821 (Fed. Cir. 1991).....	13
<i>Kemco Sales, Inc. v. Control Papers Co.</i> , 208 F.3d 1352 (Fed. Cir. 2000).....	23
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967 (Fed. Cir. 1995).....	13
<i>Oakley, Inc. v. Sunglass Hut Int’l.</i> , 316 F.3d 1331 (Fed. Cir. 2003).....	13
<i>Odetics, Inc. v. Storage Technology Corp.</i> , 185 F.3d 1259 (Fed. Cir. 1999).....	2, 23
<i>Philips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	19
<i>Texas Instruments Inc. v. U.S. Int’l Trade Comm’n</i> , 805 F.2d 1558 (Fed. Cir. 1986).....	17

<i>Warner-Jenkinson Corp. v. Hilton Davis Corp.</i> , 520 U.S. 17 (1997).....	13
--	----

<i>Waters v. City of Morristown</i> , 242 F.3d 353 (6th Cir. 2001)	13
---	----

STATUTES

35 U.S.C. § 112.....	21, 23
----------------------	--------

OTHER AUTHORITIES

Fed. R. Civ. P. 26.....	1
-------------------------	---

Fed. R. Civ. P. 56.....	1,13
-------------------------	------

Defendant Medical Device Technologies, Inc. (“MDTech”) asks for summary judgment that the accused BioPince devices (“the accused products”) do not infringe U.S. Patent No. 5,025,797 (“the ‘797 patent”) issued to Gregory W. Baran, M.D. (“Dr. Baran”). For the reasons that follow, MDTech is not entitled to summary judgment.¹

I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

MDTech requests summary judgment based on its assertion that the accused products do not meet three claim limitations of the ‘797 patent. In each instance, however, genuine issues of material fact exist that preclude entry of summary judgment against Dr. Baran. With respect to all three limitations, MDTech’s position is based on new arguments for a significantly more narrow construction than what it argued for during the claim construction phase of this case. These new arguments are:

- The charging member limitation is further limited to a member that operates directly against a guide (SJ Brief at 21);
- The cannula mount limitation is further limited to an independently fabricated structure having independent form, uniform geometry, shape, surface area, coverage, or strength (SJ Brief at 26); and
- The function of the release means for retaining limitation is further limited to release in a manner that is suitable for taking a biopsy (SJ Brief at 19).

Such new claim construction arguments are plainly improper, particularly because the Court largely adopted MDTech’s proposed constructions of these terms at the claim construction phase of this case and MDTech argues no grounds for being able to further limit the meaning of these limitations at this late stage of the case.

¹ Accompanying this Opposition are the supporting declarations of Steven M. Auvil, John R. Haaga, M.D., and Dr. Baran. Dr. Baran offers his opinion in his declaration in accordance with Fed. R. Civ. P. 56(e). There was no requirement for Dr. Baran to submit an expert report in this litigation because he was not “retained or specially employed to provide expert testimony” in this case or “one whose duties as the party’s employee regularly involve giving expert testimony.” *See* Fed. R. Civ. P. 26(a)(2); *see also Ekstam v. Ekstam*, 2007 WL 2571968, *2 (E.D. Mo. 2007) (Auvil Decl. Ex. 1). Moreover, MDTech has had the opportunity to take his deposition after Dr. Baran submitted his infringement contentions, so it has not been prejudiced by any lack of notice of Dr. Baran’s opinions.

Moreover, with respect to the third limitation, the release means for retaining limitation, MDTech's argument is based on a misunderstanding of the law of statutory equivalents and Dr. Baran's theory of infringement. MDTech's legal argument is flawed because it rests on a component-by-component analysis of the release means for retaining limitation, which is contrary to the law of statutory equivalents. *Odetics, Inc. v. Storage Technology Corp.*, 185 F.3d 1259 (Fed. Cir. 1999). MDTech's misuse argument is grounded in a straw man (*i.e.*, that Dr. Baran recommends performing a biopsy by lifting the cocking arm of the accused product) and ignores the undisputed fact that Dr. Baran's theory of use of the accused products is safe, effective, and not inconsistent with the instructions that accompany the accused products.

With neither facts nor law on MDTech's side, and any doubt of a genuine issue of material fact resolved in Dr. Baran's favor, MDTech's motion should be denied.

II. FACTUAL BACKGROUND

A. THE PARTIES

Dr. Baran is a licensed physician and a practicing radiologist since 1981. (*See* Baran Decl., ¶ 2, Ex. 1 (CV.)) In 27 years as a practicing radiologist, he has performed thousands of biopsies using manual, semiautomatic, and automatic types of needles. (*Id.*, ¶ 7.) Based on his experience, he has been published in the area of percutaneous biopsy (*i.e.*, biopsy where a needle is inserted and a tissue sample removed through the skin) and has four U.S. patents related to biopsy devices, including the '797 patent. (*Id.*)

MDTech is a Delaware corporation with a principal place of business in Florida. (Dkt. No. 67 at 2.) It acquired the BioPince product around 2002 from AMEDIC, a distributor (Auvil Decl. Ex. 2 (Ryan Dep.) at 29-33.) MDTech imports and sells the accused products in the United States. (Auvil Decl. Ex. 2 (Ryan Dep.) at 20, 27-29.)

B. THE ACCUSED PRODUCTS

The accused products are automatic biopsy instruments. The particular model shown in Fig. 1 is Model No. 360-1080-01, which includes an 18 gauge needle that is 10 cm in length. This model is representative of all originally accused models of the accused products. The originally accused models include a green cocking arm and a 16-gauge or 18-gauge needle. (Dkt. No. 164-14 (“Marcoux Decl.”), ¶¶ 2-3; Haaga Decl. Ex. 1 (Haaga Report) ¶ 29.) MDTech also sold a redesigned model (also accused of infringement) having a blue cocking arm and an 18-gauge needle. (Marcoux Decl., ¶ 2.) The redesigned model was introduced in 2007, after MDTech knew of Dr. Baran’s infringement contentions and after the Markman hearing. (*See Id.*) Except where noted below, the originally accused models and the redesigned model have the same components and are operable in the same manner.

1. Key Components of the Accused Products

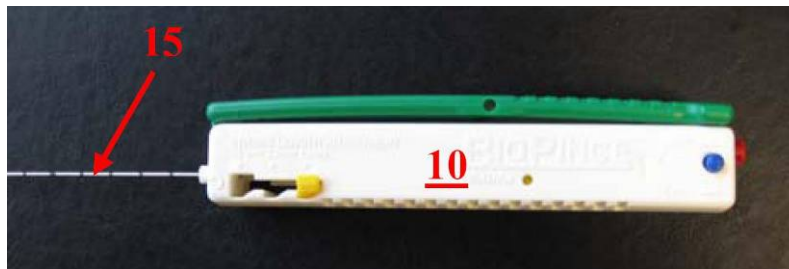


Fig. 1

As illustrated in Fig. 1, the accused products include a casing 10 with a needle 15. The needle 15 includes a cutting cannula 20 and a stylet 25, as shown in Figs. 2 and 3 below. The accused products further include a cannula guide 40 configured to guide the cutting cannula 20. A patch of adhesive 45 affixes the cutting cannula 20 to the cannula guide 40, and a spring 50 urges the guide 40 towards its discharged position. (Haaga Decl. Ex. 1 (Haaga Report), ¶¶ 41, 43, 44, 46; Auvil Decl. Ex. 3 (Rashidi Report) at 4-5.)

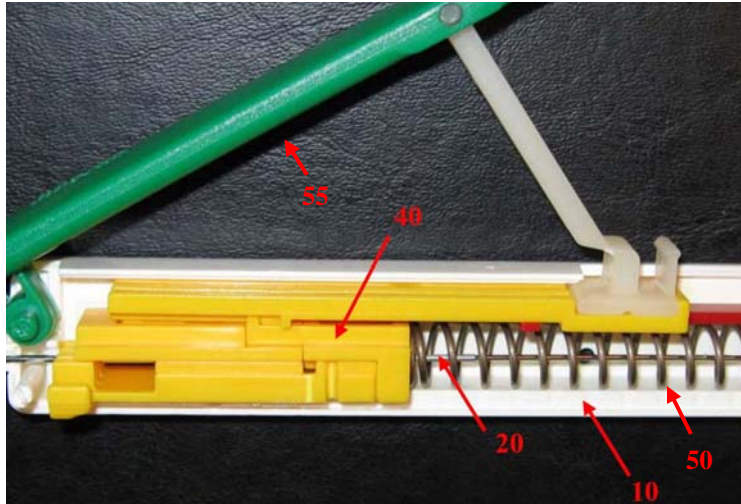


Fig. 2

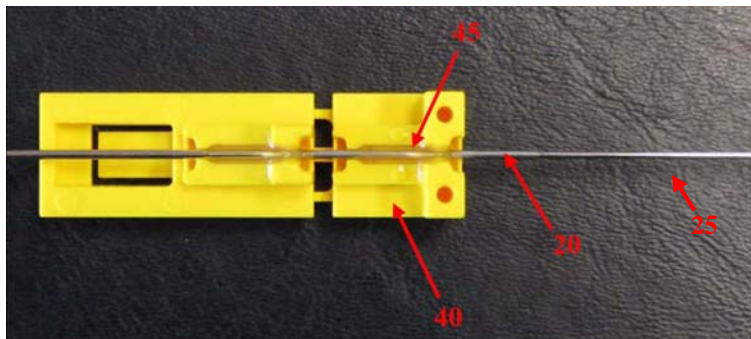


Fig. 3

As can be seen in Fig. 4, the needle further includes a sharpened stylet end 25a. Additionally, the cutting cannula 20 includes a slot 20a and is surrounded by an outer cannula 90 having a finger probe 90a. (Haaga Decl., ¶ 4; Baran Decl., ¶ 13.)

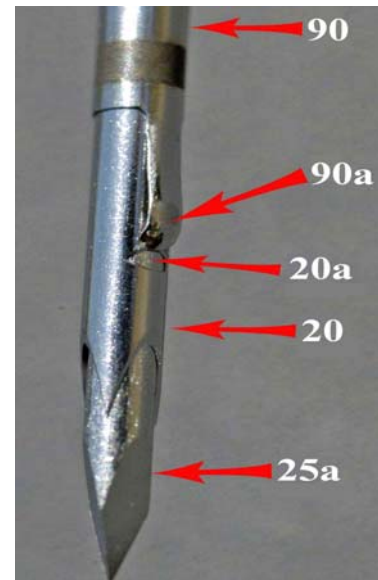


Fig. 4

The accused products also include a cocking arm 55 pivotally connected to casing 10. The cocking arm 55 is pivotally connected to a strut 60 integrally formed with a release lever 65 having a latching projection 70 and a mounting section 75. The latching projection 70 engages a shoulder 80 formed on the cocking arm 55 and accessible through opening 85. The accused products also include a firing button 100 at its proximal end. (Haaga Decl. Ex. 1 (Haaga Report), ¶¶ 47, 50; Auvil Decl. Ex. 3 (Rashidi Report) at 13.)

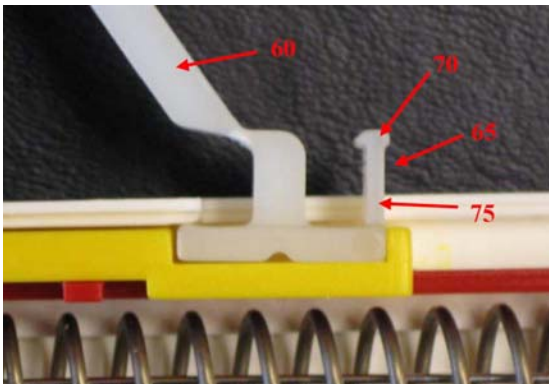


Fig. 5

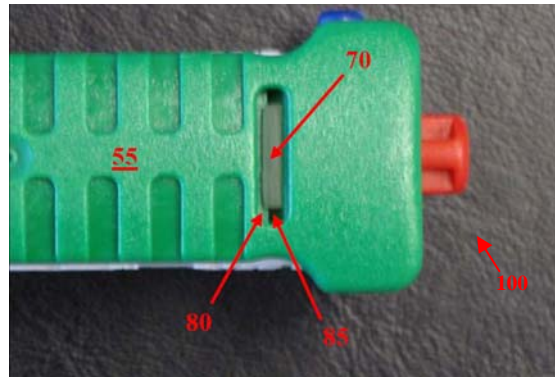


Fig. 6

2. Undisputed Operation of the Accused Products

To charge the accused product, the user lifts the cocking arm 55 until a “click” is heard and then pushes the cocking arm down against the force of the spring 50 until a second “click” is heard. The second “click” results from the latching projection 70 engaging the shoulder 80 formed on the cocking arm 55. This action moves the guide 40 from the discharged position to the charged position, against the urging of the spring 50, and retains the guide 40 in the charged position. Further, this action puts the needle in the orientation shown above in Fig. 4, with the sharpened end 25a of the stylet 25 extending in front of both the cutting cannula 20 and the outer cannula 90. (See Auvil

Decl. Ex. 4 (BioPince Manual) at MDT004145, Ex. 3 (Rashidi Report) at 13-14; Haaga Decl. Ex. 1 (Haaga Report), ¶¶ 47, 50; Baran Decl. ¶ 15.)

To perform a biopsy, the sharpened end 25a of the stylet 25 is placed at the biopsy site (*i.e.*, a location on human tissue) and the operator presses the firing button 100. This action causes the cutting cannula 20 to discharge into the tissue and capture a tissue sample. More specifically, the inner cutting cannula 20 slides over the sharpened end 25a of the stylet 25 and cuts into the human tissue. In addition, the outer cannula 90 slides over the cutting cannula such that the finger probe 90a slides into the slot 20a of cutting cannula 20. The finger probe 90a severs the tissue sample and retains it within the cutting cannula 20. The operator then removes the accused product from the patient, with the tissue sample still inside the cutting cannula 20. (*See* Auvil Decl. Ex. 4 (BioPince Manual) at MDT004145, Ex. 3 (Rashidi Report) at 13-15, Ex. 5 (Rashidi Supp. Report) at 2, Ex. 6 (Haaga Dep) at 189:17-190:12; Baran Decl. ¶ 16.)

To remove the tissue sample from the cannula, the operator repeats the step of lifting, then pushing down the cocking arm 55. By moving the cocking arm 55 in this manner, the cutting cannula 20 retracts over the stylet 25, releasing the tissue sample. The guide is again retained in a charged position with latching projection 70 engaging the shoulder 80 formed on cocking arm 55. These steps may be repeated to take multiple samples from a single patient, as the instructions note that, “[t]he instrument is now cocked for another specimen retrieval.” (*See* Auvil Decl. Ex. 4 (BioPince Manual) at MDT004145, Ex. 6 (Haaga Dep) at 190:12-191:20; Baran Decl. ¶ 17.)

The instructions are silent on the further operation of the accused product, but note that they are *not* meant to suggest any medical or surgical technique, giving

deference to the physician for determining the proper procedure. (*See* Auvil Decl. Ex. 4 (BioPince Manual) at MDT004145.) The parties dispute what would happen next.

3. Disputed Operation of the Accused Products

MDTech asserts that it is improper to discharge the accused products by lifting up on the cocking arm 55, whether or not it is to perform a biopsy. (SJ Brief at 13-17.) Dr. Baran acknowledges that this is not the preferred way to take a biopsy of live human tissue. But it is undisputed that (1) a loaded biopsy gun is a potentially dangerous device (Auvil Decl. Ex. 6 (Haaga Dep.) at 192:14-193:7 and 199:4-200:14, Ex. 7 (Rashidi Dep.) at 228:10-229:15; Baran Decl. ¶¶ 23, 30, Exs. 14-17 (FDA Reports 774237, 665790, 1221697, 1030035;)) (2) the instructions accompanying the accused products do not state or suggest that lifting the cocking arm is inadvisable (Auvil Decl. Ex. 4 (BioPince Manual) at MDT004145); and (3) there are distinct advantages associated with discharging the device by lifting the cocking arm 55 over pressing the firing button 100 (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶¶ 23-31.).

The first such advantage is the needle 15 is more likely to be damaged when the accused product is discharged “in air” (*i.e.*, discharging the device without attempting to take a biopsy) by pressing the firing button 100. (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶¶ 23-28.) When the accused product is outside of the patient, pressing the firing button 90 may damage the needle in multiple ways. As explained above, when the accused product is discharged by pressing the firing button, the finger probe 90a enters the slot 20a. The finger probe 90a is thin and susceptible to damage when it moves into the slot 20a at high speed, without lubrication. (Baran Decl., ¶ 24; Haaga Decl., ¶ 4.)

In fact, multiple Federal Drug Administration (FDA) reports describe needle damage. (Baran Decl. Exs. 5-13 (FDA Reports 569592, 867390, 878869, 874151, 874149, 907103, 1014919, 1004744, 1046809, 569592.)) One FDA report, in particular, noted that a piece of an accused product was observed missing and noted, “it is believed that the customer may have fired the device inappropriately prior to use, as well as after.” (Baran Decl. Exs. 5 (FDA Report 569592.))

By contrast, as shown in Fig. 7 below, it is undisputed that when an accused product is discharged by lifting the cocking arm 55, the finger probe 90a maintains its position relative to the slot 20a, and does not enter slot 20a. (Auvil Decl. Ex. 5 (Rashidi Supp. Report) at 2; Baran Decl., ¶ 24; Haaga Decl., ¶ 5.) MDTech characterizes the finger probe 90a as “inoperable” when discharged in this manner (SJ Brief at 15), but in fact, when discharging the accused products in air, lifting the cocking arm prevents damage that may be caused to the finger probe 90a by entering the slot 20a at high speed without lubrication. (Baran Decl., ¶ 24; Haaga Decl., ¶ 5.)

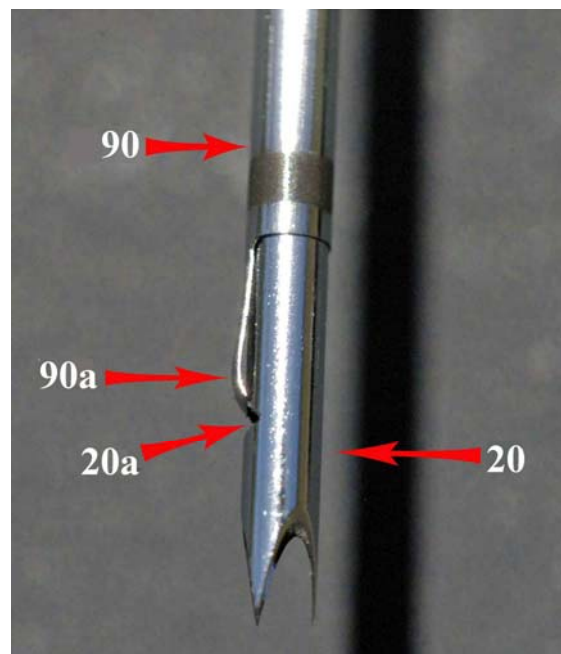


Fig. 7

Further, discharging the device in air by pressing the firing button may cause burring on the needle. (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶¶ 25-26.) “Burring” is the forming of rough edges in metal, such as barbs and shards (also known as “burrs”). (See Auvil Decl. Exs. 8 (McGraw-Hill Dictionary of Scientific and Technical Terms, 2003) and 9 (Webster’s Third New International Dictionary, 2002.)) Burring may occur when the metal cannulas of the accused products move at high speed, without lubrication, relative to each other and to the metal stylet. (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶ 25.) Burrs that are formed would complicate later biopsies on the patient. (See, e.g., Baran Decl. Ex. 13 (FDA Adverse Event Report 1046809.)) Such burring does not occur when the accused product is discharged in tissue, because the tissue lubricates and slows down the needle. (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶ 25.)

Burring is a well-known problem with automatic and semi-automatic biopsy devices. (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶ 26; Baran Decl. Ex. 13 (FDA Adverse Event Report 1046809.)) To prevent burring of the needle on the accused product, it may be discharged by lifting the cocking arm 55 rather than pressing the firing button. (Haaga Decl., ¶ 5; Baran Decl. ¶ 26.) Discharging the accused product in this manner allows the user to control the speed of the discharge, thereby preventing burrs from forming. (Haaga Decl., ¶ 5; Baran Decl. ¶ 26.) MDTech’s expert, Majid Rashidi, Ph.D., P.E. (“Dr. Rashidi”), acknowledged that a user can control the speed of discharge by lifting the cocking arm. (Auvil Decl. Ex. 7 (Rashidi Dep.) at 217:21-218:2.)

Another advantage associated with discharging the device by lifting the cocking arm 55 is that it less difficult for an observer to determine if the device is charged or

discharged. (Auvil Decl. Ex. 7 (Rashidi Dep.) at 174:9-20; Baran Decl., ¶ 29; Haaga Decl., ¶ 6.) When an accused product is discharged by lifting the cocking arm 55, the raised cocking arm 55 provides a universal indicator that the accused product is discharged. (Baran Decl., ¶ 29; Haaga Decl., ¶ 6.) Although the accused products do include a small (3mm) window that purportedly indicates whether the accused product is charged (Dkt. 164-2 (“SJ Brief”) at 17, n. 4), this window is not highly visible and provides insufficient notice that the device is charged. (Baran Decl., ¶ 29; Haaga Decl., ¶ 6.) In fact, MDTech’s own expert, Dr. Rashidi, even testified that when the cocking arm is closed, one could not tell whether the accused product was charged. (Auvil Decl. Ex. 7 (Rashidi Dep.) at 174:9-20.)

C. THE DISPUTED LIMITATIONS AND THEIR CONSTRUCTION

MDTech’s motion for summary judgment of non-infringement of claim 7 of the ‘797 patent² is based on the alleged absence of three limitations in the accused products. The three limitations are: 1) “a manually operable charging member for moving the guide to the charged position;” 2) “a cannula mount affixing the cannula to a guide;” or 3) “a release means for retaining a guide in a charged position.” (SJ Brief at 11.) The construction of each of these terms was disputed by the parties, and resolved by the Court in its Markman Order. (Dkt. No. 132 (“Markman Order.”))

MDTech submitted its Markman Brief on July 29, 2005 (Dkt. No. 54 (“MDTech Markman Brief”)), nearly two months after it received Dr. Baran’s infringement contentions that stated in detail how the accused products incorporate each element of claim 7 of the ‘797 patent. (*See* Auvil Decl. Ex. 10 (Baran Response to Interrogatories)

² A detailed discussion of the ‘797 patent and the preferred embodiments is provided in the Court’s Markman Order at 14-16.

at 9-15.) For example, Dr. Baran identified the cocking arm as the “manually operable charging member for moving the guide to the charged position,” and further identified the patch of adhesive as the “a cannula mount affixing the cannula to a guide.” (*Id.*)

Having been apprised of Dr. Baran’s infringement position, MDTech argued to the Court that “a manually operable charging member for moving the guide to the charged position” should be construed to mean “a charging member operable by means of the hand for moving the guide to the charged position against the urging of the coil spring.” (MDTech Markman Brief at 11-13.) MDTech did not argue that the term required a charging member to act directly on the guide. (*See id.*) Instead, MDTech opposed Dr. Baran’s argument that the term “member” did not encompass a “mechanism.” (*Id.*) MDTech did not argue the converse—that a mechanism could not include a member. At the Markman hearing, counsel for MDTech acknowledged that a member “is a constituent part of a whole.” (Markman Hearing Transcript at 89:4.)

The Court agreed with MDTech, and held the term to mean “a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring.” (Markman Order at 26.)

MDTech also argued that “a cannula mount affixing the cannula to a guide” should be construed to mean “a support which attaches the cutting cannula to the guide in a secured manner.” (MDTech Markman Brief at 8-11.) But it did not assert that the cannula mount required independent form, uniform geometry, shape, surface area, coverage, or strength. (*Id.*) And although MDTech discussed whether a cannula mount could include adhesive, it never asked for a construction that expressly used a negative

limitation (*i.e.*, “not an adhesive”) (*id.*) nor did the Court provide a negative limitation in its construction. Instead, it adopted MDTech’s proposed construction, with two minor modifications (adding the word “structure” and deleting the word “cutting”) and held the term to mean “a structure or support which attaches or connects the cannula to the guide.” (Markman Order at 19-20.)

Finally, the parties disputed the meaning of the term “a release means for retaining a guide in a charged position.” Both sides agreed this to be a means-plus-function limitation, with MDTech arguing that the function was “retaining the guide in the charged position *and* releasing the guide from the charged position.” (MDTech Markman Brief at 14, emphasis in original.) MDTech never argued that the function included releasing the guide *in a manner that is suitable for taking a biopsy*. In fact, at the Markman Hearing, counsel for MDTech observed that “[r]elease doesn’t mean any specific thing but ‘release.’” (Markman Hearing Transcript at 83:20-21.) The Court accepted the function proffered by MDTech and held the term to mean “the release lever 22, including the latching projection 102, the finger rest 96, and mounting section 98, as well as the equivalents thereof;” and “the release lever 222, including latching projection 302, the finger rest (not marked by a reference numeral), and the mounting section 298, as well as the equivalents thereof.” (Markman Order at 33.)

In light of the Court’s construction of the foregoing three limitations and for the reasons that follow, there are disputed issues of material fact that prevent summary judgment in MDTech’s favor.

III.LEGAL STANDARDS

A. LEGAL STANDARDS FOR SUMMARY JUDGMENT

Summary judgment is only appropriate where the pleadings and evidence submitted show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. The movant bears the initial burden of showing the absence of a genuine issue of material fact as to an essential element of the non-movant's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Waters v. City of Morristown*, 242 F.3d 353, 358 (6th Cir. 2001). Summary judgment should not be granted "where there is reason to believe that the better course would be to proceed to a full trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Any doubt as to the existence of a genuine issue for trial should be resolved in favor of the non-movant. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 158-159 (1970).

B. LEGAL STANDARD FOR LITERAL INFRINGEMENT

To prove infringement, Dr. Baran bears the burden of showing that the accused products meet the asserted claims. *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378-79 (Fed. Cir. 2007) (citing *Warner-Jenkinson Corp. v. Hilton Davis Corp.*, 520 U.S. 17 (1997)). Infringement analysis is a two-step process requiring: 1) a determination of the scope and meaning of the asserted patent claims; and 2) a comparison of the claims to the accused product. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003). The first step, claim construction, is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). The second step, the comparison of the claims to the accused product, is a question of fact. *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821 (Fed. Cir. 1991).

In moving for summary judgment of no infringement, MDTech bears the burden of showing the absence of a genuine issue of material fact on the question of infringement. In other words, MDTech bears the burden of showing that no genuine issue of material fact exists regarding infringement, such that no reasonable jury could find in favor of Dr. Baran. *See In re Gabapentin Patent Litigation*, 503 F.3d 1254, 1259 (Fed. Cir. 2007).

IV. ARGUMENT

In its Summary Judgment Brief, MDTech alleges that the accused products do not infringe the ‘797 patent as a matter of law because they do not have: 1) “a manually operable charging member for moving the guide to the charged position;” 2) “a cannula mount affixing the cannula to a guide;” or 3) “a release means for retaining a guide in a charged position.”³ However, as demonstrated below, genuine issues of material fact exist relating to whether the accused products meet these limitations, precluding summary judgment in MDTech’s favor.

A. THE ACCUSED PRODUCTS INCLUDE A MANUALLY OPERABLE CHARGING MEMBER FOR MOVING THE GUIDE TO THE CHARGED POSITION AGAINST THE URGING OF THE COIL SPRING

The Court construed “a manually operable charging member for moving the guide to the charged position against the urging of the coil spring” – “the charging member limitation” – to mean “a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring.” (Markman Order at 26.) The principal claim construction dispute was whether the term “member” should be defined to

³ For purposes of summary judgment, MDTech has conceded that the accused products meet all other limitations of the asserted claim of the ‘797 patent.

include “mechanism.” (*Id.* at 20.) The Court concluded that “member” does not include “mechanism,” but held that it “only determines what ‘member’ is *not*; it does not determine how it should be defined.” (*Id.* at 25, emphasis in original.) Contrary to what MDTech argues in support of summary judgment, *the Court did not rule that the claimed charging member cannot be part of a mechanism that moves the guide to the charged position*, nor did MDTech even argue for such a construction.

Dr. Baran identified the cocking arm 55 as a manually operable charging member in his infringement contentions served on MDTech in 2005. (Auvil Decl. Ex. 10 (Baran Response to Interrogatories) at 11-13.) After the Markman Order was issued, Dr. Baran re-asserted this contention through his expert, Dr. Haaga.⁴ (Haaga Decl. Ex. 1 (Haaga Report), ¶ 47.) Dr. Haaga’s Expert Report raises issues of fact regarding the identified charging member, most of which are undisputed by MDTech.

It is undisputed that the cocking arm 55 is manually operable. (Auvil Decl. Ex. 7 (Rashidi Dep.) at 170:6-8.) Additionally, MDTech admits in its own brief that movement of the cocking arm 55 towards the casing causes the guide 40 to move to its charged position against the urging of the coil spring 50. (SJ Brief at 25; *see also* Haaga Decl. Ex. 1 (Haaga Report), ¶ 47; Baran Decl. ¶ 15.) In fact, the accused products are marked with U.S. Patent No. 6,322,523 (“the ‘523 patent”), which refers to the identified

⁴ MDTech questions the qualifications of Dr. Haaga, dismissing him as merely a “knowledgeable doctor, who has a lay person’s understanding of the reasons why the devices operate as they do.” (SJ Brief at 7.) While Dr. Haaga is indeed a knowledgeable doctor, he is not merely a person who ordinarily uses the product, but is a pioneer in biopsy procedures and has several patents directed to biopsy devices. (*See* Haaga Decl. Ex. 1 (Haaga Report), Ex.1 (Haaga CV.)) As a pioneer in the field, Dr. Haaga understands the problem to be solved and is the type of person who would be expected to solve such problems. MDTech asserts that Dr. Haaga is unfamiliar with certain legal terms (SJ Brief at 7-8), but this does not detract from his technical acumen. The relevant art (spring-loaded biopsy instruments), while mechanical in nature, is not so complex as to be beyond the understanding of someone with clinical experience in performing biopsies and an understanding of basic mechanics. Indeed, MDTech’s own expert, Dr. Rashidi testified that “it is a very simple device, very, very simple device.” (Auvil Decl. Ex. 7 (Rashidi Dep.) at 70:15-16.)

component as a “loading arm 520” that works with other components to compress the spring. (Auvil Decl. Ex. 11 (Blake Dep.) at 96:1-10, Ex. 12 (photo of Ex. 30A to Blake Dep.), Ex. 13 (the ‘523 patent) at col. 6, lines 45-49.) Based on these facts alone, a reasonable juror could find that the cocking arm of the accused products meet the charging member limitation.

To be sure, the cocking arm 55 of the accused products acts in concert with other members to move the guide member to a charged position. But neither the charging member limitation itself nor the Court’s construction of it requires that the charging member alone move the guide to the charged position. Nor did MDTech ever ask for such a construction, despite knowing that it was Dr. Baran’s contention all along that the charging member limitation was met by the cocking arm alone. (Auvil Decl. Ex. 10 (Baran Response to Interrogatories) at 11-13.)

MD Tech tries to compensate for the weakness of its legal position by arguing that “Haaga admits that the ‘797 patent *requires* a member that *directly* charges the device.” (SJ Brief at 21, emphasis added.) But MDTech’s support for this statement is a quote from the transcript of Haaga’s deposition in which Dr. Haaga was discussing a *preferred embodiment* described in the ‘797 patent. (Auvil Decl. Ex. 6 (Haaga Dep.) at 166:25-167:6.) Even so, MDTech cites no authority for the proposition that a technical expert’s post-Markman admissions can further limit claims.

In effect, what MDTech endeavors to do is re-argue claim construction without saying so. But it is too late to argue further limitations to claim language, and MDtech can offer no legitimate reason for doing re-opening claim construction.

Moreover, even if new claim construction arguments were properly before the Court, MDTech disregards a cardinal rule of claim construction by trying to limit the charging member limitation to conform narrowly to the preferred embodiment. Although it is proper in some circumstances to so limit the scope of claims, such as when there is a clear disavowal of claim scope, it is not proper here, nor does MDTech argue that it is. Whether the accused products have a mechanism has no bearing on infringement. The issue is whether the accused products have a member that meets the charging member limitation. And in that regard MDTech's own expert, Dr. Rashidi, acknowledged that that a member can be part of a mechanism, testifying that the cocking arm "is *one member of a mechanism* which I'm calling it a slider crank which collectively together, these three members, charge the spring" and further testified that the cocking arm is "absolutely" a member of that mechanism.⁵ (Auvil Decl. Ex. 7 (Rashidi Dep.) at 168:9-12, 170:19-25.) Dr. Rashidi also acknowledged that the accused products could not be charged without the cocking arm. (*Id.* at 169:24-170:1.)

Ignoring its expert's sworn testimony, MDTech presses forward with discussing the advantages of a multiple member mechanism. (SJ Brief at 22.) However, any mechanical advantage of a slider-crank mechanism is simply not relevant to infringement. The Federal Circuit has held that "[a]s a matter of law, subsequent improvements do not in themselves preclude a finding of infringement." *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1568 (Fed. Cir. 1986).

In sum, and in view of the requirement of resolving doubts in Dr. Baran's favor, MDTech's arguments are insufficient to show an absence of a genuine issue of material

⁵ Moreover, a reasonable juror can rely on everyday experience to conclude that a manually operable member can be configured to perform a task in cooperation with other members. In that regard, a handle on a toilet is a manually operable flushing member.

fact with respect to the charging member limitation, and therefore, summary judgment as to this element should be denied.

B. THE ACCUSED PRODUCTS INCLUDE A CANNULA MOUNT AFFIXING THE CANNULA TO THE GUIDE

The Court construed “a cannula mount affixing the cannula to the guide” – “the cannula mount limitation” - to mean “a structure *or support* which attaches or connects the cannula to the guide.” (Markman Order at 19-20, emphasis added.) Prior to issuance of the Markman Order, Dr. Baran identified a patch of adhesive as the cannula mount that affixes the cannula to the guide as the corresponding element in the accused product. (Auvil Decl. Ex. 10 (Baran Response to Interrogatories) at 10.) And after the Court construed the cannula mount limitation, Dr. Haaga similarly identified the adhesive patch as the structure or support in the accused products that attaches or connects the cannula to the guide. (Haaga Decl. Ex. 1 (Haaga Report), ¶ 44; Fig. 8.)

MDTech does not dispute that the identified adhesive is a *support* that attaches or connects the cannula to the guide, so it has not met its burden of showing that no material fact issue exists relating to the cannula mount limitation for this reason alone. Whether MDTech will attempt to wriggle out of this predicament by trying to equate “support” and “structure” remains to be seen, but doing so in a reply brief would be improper. Moreover, there is no basis for doing so as these terms have different meanings.⁶

MDTech does argue that the adhesive patch is not a structure, but this is a disputed issue of material fact. (See Haaga Decl. Ex. 1 (Haaga Report), ¶ 44, Fig. 8;

⁶ See Auvil Ex. 9 (Webster’s Third New Int’l Dictionary, 2002) (defining “structure” as “something having definite or fixed pattern of organization” (noting “any object which is in some sense an organized whole is said to have, or to be characterized by, [structure]”)); and defining “support” (n) as “one that supports” [where “support” (v) is defined as “to hold up or in position; serve as a foundation or prop for; bear the weight or stress of; keep from sinking or falling”]).

Auvil Decl. Ex. 6 (Haaga Dep.) at 122:12-123:8.) MDTech's attempt to argue around this disputed fact again smacks of re-arguing claim construction.

Specifically, MDTech asserts that adhesive is not a structure because it has "no independent form, uniform geometry, shape, surface area, coverage, or strength" and is not "independently fabricated." (SJ Brief at 26.) But the Court's construction of the cannula mount limitation does not impose such requirements. (*See* Markman Order at 19-20.)⁷ Moreover, MDTech never asked the Court to impose such requirements in its proposed construction of this limitation, and the Court adopted MDTech's proposed construction with minor changes. As such, MDTech's attempt to graft additional limitations on the cannula mount limitation at this late stage should not be permitted.

Even if the Court were to permit MDTech to re-open claim construction at this stage of the case, MDTech's positions are without merit. First, MDTech principally relies on disfavored extrinsic evidence to support its new construction of the cannula mount limitation. That evidence comes in the form of expert opinion testimony and cherry-picked definitions from dictionaries, both of which are suspect. *See Philips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons.") Second, MDTech tries to limit the claimed "cannula mount" to the preferred embodiment of the '797 patent, without any legal basis for doing so. In sum, nothing would be gained by re-opening claim construction, as MDTech's position are not well grounded in law.

⁷ To be sure, the Court did comment that the '797 patent claims a "piece or structure which is independent from the structures of the guide and the cannula" (Markman Order at 19), but MDTech goes too far in reading this comment as a requirement for "independent form, uniform geometry, shape, surface area, coverage, or strength" or "independent fabrication". (*See* SJ Brief at 26.) Moreover the patch of adhesive is a piece or structure independent from the guide and the cannula. (Baran Decl. ¶ 47.)

MDTech's argument on the facts fares no better. Specifically, whether "structure" includes an adhesive patch is a genuine issue of material fact. An MDTech witness testified that the adhesive used in the accused products is an epoxy. (Auvil Decl. Ex. 11 (Blake Dep.) at 87-88, 93.) An epoxy is defined as "any of various usually thermosetting resins capable of forming tight cross-linked polymer *structures* characterized by toughness, strong adhesion, and low shrinkage, used especially in surface coatings and adhesives." (The American Heritage Dictionary of the English Language, 4th Ed., 2006.)⁸ Dr. Haaga opines that such a hardened polymer is a structure, and that is supported by other evidence. (Auvil Decl. Ex. 6 (Haaga Dep.) at 122:12-123:8; Baran Decl. ¶¶ 43-51.)

During the manufacturing process for the accused products, the cannula is placed in a v-shaped groove in the guide and "is merely laying in there" before epoxy is applied. (Auvil Decl. Ex. 11 (Blake Dep.) at 94.) There is not a tight fit between the groove and the cannula. (Auvil Decl. Ex. 11 (Blake Dep.) at 94.) In other words, the cannula is affixed to the guide only by virtue of the presence of the epoxy. When epoxy is applied to the area and cures into a hardened state, the epoxy holds the cannula in place and provides support. (Auvil Decl. Ex. 6 (Haaga Dep.) at 145:12-25.)

Further, as mentioned above, the accused products are marked with the '523 patent, which states "FIG. 1 shows the rear portion of the canula [sic, cannula] 101 *mounted* to its holder 100 *by gluing*." (Auvil Decl. Ex. 13 ('523 Patent) at col. 4, lines 16-17.) MDTech dismisses this evidence by arguing that there is a distinction between

⁸ See also Auvil Decl. Ex. 8 (McGraw-Hill Dictionary of Scientific and Technical Terms, 2003) (Defining "epoxy resin" as "[a] polyether resin... having high strength, and low shrinkage during curing; used as a coating, adhesive, casting, or foam" [where "casting" is defined as "any object which is formed by placing a castable substance in a mold or form and allowing it to solidify"]).

“the verb, ‘mount’ and the noun that is called for in the claim limitations.” (SJ Brief at 27.) MDTech does not explain this distinction, nor can it. It is axiomatic that something which performs the act of mounting is, itself, a mount.

In short, affording Dr. Baran the benefit of the doubt, MDTech’s arguments are insufficient to show an absence of a genuine issue of material fact with respect to the cannula mount limitation, and summary judgment as to this element should be denied.

**C. THE ACCUSED PRODUCTS INCLUDE A RELEASE MEANS FOR
RETAINING THE GUIDE IN THE CHARGED POSITION**

The Court construed the term “release means for retaining the guide in the charged position” – “the release means for retaining limitation” – as a means-plus-function limitation in accordance with 35 U.S.C. § 112, ¶ 6. (Markman Order at 26.) The Court held the function of this element to be “retaining the guide in the charged position and releasing, or setting free, the guide from the charged position” (Markman Order at 30-31) and identified the corresponding structure in the disposable embodiment of the ‘797 patent as “the release lever 222, including latching projection 302, the finger rest (not marked by a reference numeral), and the mounting section 298, as well as the equivalents thereof.” Markman Order at 33.

Prior to the Court’s Markman Order, Dr. Baran identified the “release means for retaining” in the accused products as “a latch [65] configured to engage a notch [85] in handle lever [or cocking arm 55] to retain guide [40] in the charged position.” (Auvil Decl. Ex. 10 (Baran Response to Interrogatories) at 11-13.) After the Markman Order was issued, Dr. Haaga elaborated on this position, identifying the release lever 65 with the latching projection 70 and mounting section 75 as the components that both retain and release the guide 40. (Haaga Decl. Ex. 1 (Haaga Report), ¶ 50; *see* Figs. 5 and 6,

reproduced below.) During his deposition, Dr. Haaga explained how the structure of the accused product had the same “functionality,” “intervening steps,” and “outcome” as the release means for retaining limitation. (Auvil Decl. Ex. 6 (Haaga Dep.) at 76-78.) This evidence sufficient to raise an issue of material fact with respect to whether the release means for retaining limitation is met in the accused products.

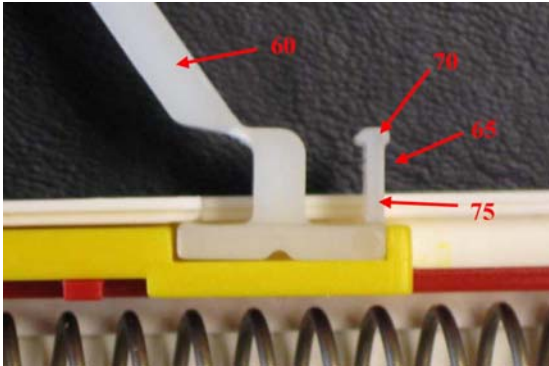


Fig. 5 (reprint)

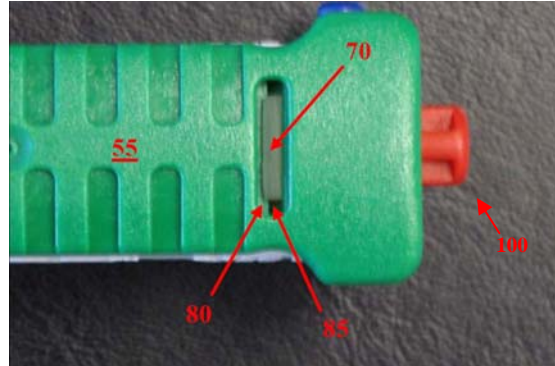


Fig. 6 (reprint)

Before addressing those components identified by Dr. Baran (including through Dr. Haaga) as a structural equivalent to the release means for retaining limitation, MDTech focuses on components of the accused product that were never identified as a structural equivalent, namely the firing button and related components. However, the factual dispute is over that structure identified by Dr. Baran, not the firing button and related components.

When MDTech does turn its attention to the structural equivalent identified by Dr. Baran, it fails to apply the proper legal standard. MDTech offers a component-by-component analysis of the accused product to the structure in the ‘797 patent that corresponds to the claimed function, asserting that the release lever is not a lever and does not have a finger rest. (SJ Brief at 18.) But this approach is contrary to law. For § 112, ¶ 6 equivalents, “a party may prove it is equivalent to the disclosed structure by showing that the two perform the identical function in substantially the same way, with

substantially the same result.” *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324 (Fed. Cir. 2006) (citing *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1364 (Fed. Cir. 2000)).

By contrast, the Federal Circuit has criticized the component-by-component approach MDTech takes, noting:

The individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function. This is why structures with different numbers of parts may still be equivalent under § 112, ¶ 6, thereby meeting the claim limitation.

Odetics, 185 F.3d at 1268. By applying the wrong test, MDTech cannot be said to meet its burden of showing the absence of a genuine issue of material fact.

In spite of its own improper analysis of structural equivalents, MDTech faults Dr. Haaga (a non-lawyer) for failing to articulate the meaning of equivalents (SJ Brief at 10). Again, however, MDTech appears to confuse statutory equivalents with the doctrine of equivalents, but they are distinct bodies of law with different requirements.⁹ Under the applicable legal standards associated with statutory equivalents, Dr. Baran’s testimony and Dr. Haaga’s testimony, taken alone or in combination, are each sufficient to support Dr. Baran’s claim and adequate to defeat summary judgment on this issue, particularly in light of the requirement that doubts be resolved in Dr. Baran’s favor.

1. The Release Means for Retaining in the Accused Products Perform the Identical Function as in the Claimed Invention

The accused products include a release lever 65 that includes a latching projection and a mounting section that, together, perform the function of retaining the guide in the

⁹ For example, unlike the doctrine of equivalents, equivalents under 35 U.S.C. § 112 does not require particularized testimony and linking arguments for each part of the tripartite test. *Applied Med. Res. Corp.*, at 1335 n. 5 (Fed. Cir. 2006).

charged position and releasing, or setting free, the guide from the charged position (*See* Haaga Decl. Ex. 1 (Haaga Report), ¶ 50; Auvil Decl. Ex. 6 (Haaga Dep.) at 180, 182-83; Baran Decl. ¶ 52.) Both the retaining and releasing function of these components are demonstrated in the video submitted herewith. (Baran Decl. Ex. 2 (Video.))

MDTech focuses on a slider link and front guide, again addressing additional components and functionality that is not relevant to Dr. Baran's infringement contentions. (SJ Brief at 13.) These components addressed by MDTech have never been identified by Dr. Baran as a structural equivalent of the release means for retaining. Whether they also perform the function of retaining the guide in the charged position and releasing, or setting free, the guide from the charged position is of no import. *See Canon Computer Sys., Inc. v. Nu-Kote Int'l Inc.*, 134 F.3d 1085 (Fed. Cir. 1998) ("It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device.")

MDTech does not dispute that the structure identified by Dr. Baran performs the identical function of retaining the guide in the charged position. MDTech does argue that the identified structure does not release the guide "in a manner that is suitable for taking a biopsy," (SJ Brief at 19) but this added qualification was not part of the function identified by the Court. The claims are not specific to a method of taking a sample of human tissue, and it is erroneous to import unclaimed functions into a means-plus-function limitation. *See Applied Med. Res. Corp.*, 448 F.3d at 1334.

2. The Release Means for Retaining in the Accused Products Operate in Substantially the Same Way as in the Claimed Invention

The release means for retaining in the accused products operates as follows: i) when the latching projection 70 engages the shoulder 80 of the cocking arm 55, the guide

is retained in its charged position and ii) when the latching projection 70 is disengaged from the shoulder 80 in the opening 85 of the cocking arm 55 (e.g., by lifting up on the cocking arm 55), the guide is released or set free from its charged position. (Haaga Decl. Ex. 1 (Haaga Report), ¶ 50; Baran Decl. ¶ 54.)

MDTech acknowledges, as it must, that the guide member is retained in the charged position when the cocking arm is closed. (SJ Brief at 13.) MDTech also does not dispute that the guide is released from the charged position when a user lifts the cocking arm, as Dr. Haaga described. Instead, MDTech argues that the guide is released in a different way from the claimed invention, stating that when the cocking arm is lifted, it pulls the shoulder out from under the tab of the release lever. (SJ Brief at 20.) While the shoulder of the opening does move laterally, it also moves upwards, pressing against the latching projection, causing the release lever to flex proximally, as Dr. Haaga noted in his corrected deposition transcript. (Auvil Decl. Ex. 6 (Haaga Dep.) Errata sheet correcting 198:14; *see also* Baran Decl. ¶ 55.) This flexing of the release lever is demonstrably shown in the attached video, a still frame of which is shown below as Fig. 8. (Baran Decl. Ex. 2 (Video.)) The flexing of the release lever causes the guide to be released in substantially the same way as the flexing of the lever in the claimed invention. (Baran Decl. ¶ 58; Haaga Decl. Ex. 1 (Haaga Report), ¶ 50; Auvil Decl. Ex. 6 (Haaga Dep.) at 76-78.)

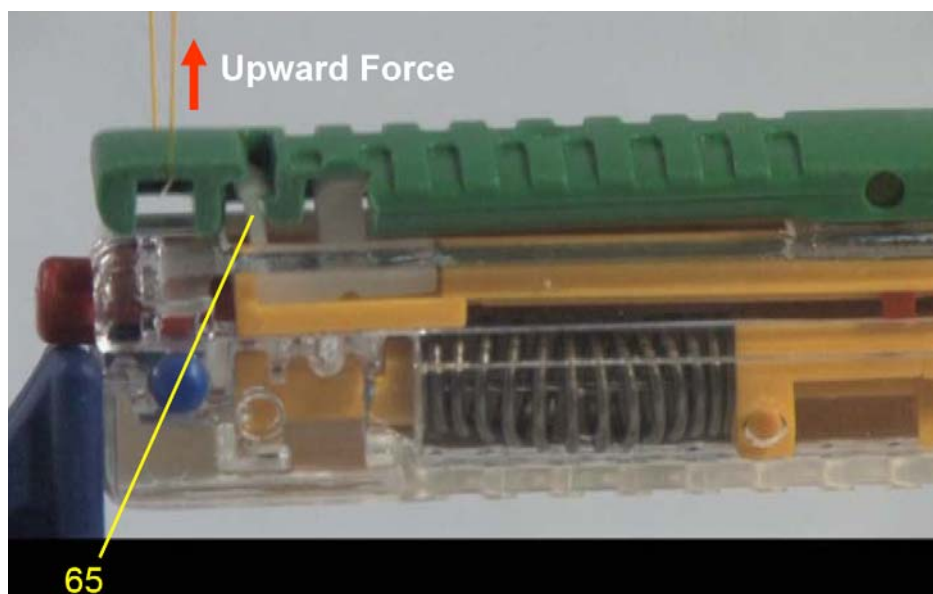


Fig. 8

3. The Release Means for Retaining in the Accused Products Produce Substantially the Same Result as in the Claimed Invention

When the identified structure of the accused products is operated in the manner described above, the guide is retained in a charged position, and then released or set free from this position, yielding substantially the same result as the claimed element. (*See* Haaga Decl. Ex. 1 (Haaga Report), ¶ 50; Baran Decl. ¶¶ 52-61.) MDTech does not address the “result” aspect of the test, except to import a condition on the result—that the release occur “in a controlled enough manner to permit a user to perform a biopsy on a patient.” (SJ Brief at 20.) This argument presumes use inside of a patient to perform a biopsy. But the claim is not so limited, nor is the Court’s construction, nor did MDTech previously ask for such a construction. The claim is directed to a biopsy instrument, not a method for performing a biopsy. Because the accused product may be discharged inside or outside of a patient, the result is simply the release of the guide, not a release in any particular manner. This result is achieved by the identified structure in the accused products. (Auvil Decl. Ex. 6 (Haaga Dep.) at 77:25-78:14; Baran Decl. ¶ 59.)

4. Dr. Baran Does not Advocate an Improper Use of the Accused Products

MDTech claims it would be improper to discharge the accused products in the manner described.¹⁰ (SJ Brief at 13-14.) But MDTech only offers evidence showing that it would be improper to lift the cocking arm to take a biopsy. (SJ Brief at 13-14, *citing* Haaga Dep. 204:19-205:2 and Rashidi Report 35-36.) As with any biopsy device, however, the accused products may be discharged (i) in a patient (*i.e.*, to take a specimen of tissue), or (ii) outside of a patient “in air” (*i.e.*, as a safety precaution to prevent accidental discharge). (See Auvil Decl. Ex. 7 (Rashidi Dep.) at 228:10-229:15 Ex. 6 (Haaga Dep.) at 199:4-200:14; Baran Decl., ¶ 23.)

MDTech offers no explanation why it would be improper to lift the cocking arm to discharge the accused product outside of a patient. Instead, it dismisses this scenario as “somewhat far-fetched, given that this is a disposable, single use device.” (SJ Brief at 17.) But this is a mischaracterization of the accused products. Although the accused product is disposable, it is designed to take multiple samples from a single patient. Indeed, MDTech’s own marketing material notes that the needle design allows for “multiple site biopsies” (Auvil Decl. Ex. 4 (BioPince Manual) at MDT004141, *emphasis added*) and the instructions state that, by cocking the accused product to discharge a specimen, “[t]he instrument is now cocked for another specimen retrieval.” (Auvil Decl. Ex. 4 (BioPince Manual) at MDT004143, MDT004145.) Likewise, MDTech’s expert, Dr. Rashidi testified in deposition that the accused products could be used multiple times on a single patient, stating “you can use it ten times on the same patient, different parts of the tumor or whatever.” (Auvil Decl. Ex. 7 (Rashidi Dep.) at 112:7-17.)

¹⁰ MDTech also cites to case law related to alterations and modifications of products, but this is not relevant here. Dr. Baran is not proposing any physical alteration to the device, but is discussing the operation of the device as it is currently designed.

As discussed above, there are at least two reasons to discharge the accused products by lifting the cocking arm rather than pressing the firing button. First, use of the firing button “in air” may damage the needle. (Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶¶ 23-28.) When outside of a patient, discharging the accused product in a controlled manner will prevent needle damage. (Haaga Decl., ¶ 5; Baran Decl. ¶¶ 25-26.) MDTech’s expert testified that when the cocking arm is manually lifted, the user can control the speed at which the accused product is discharged. (Auvil Decl. Ex. 7 (Rashidi Dep.) at 217:21-218:2.)¹¹ Lifting the cocking arm in this controlled manner is not “violent and difficult to control” as MDTech claims (SJ Brief at 14), as is shown in the demonstrative video. (Baran Decl. Ex. 2 (Video) Demo 4.) Further, discharging the accused product in this manner prevents the finger probe from entering the slot of the cutting cannula, thereby negating the risk of damage to the finger probe. (Haaga Decl., ¶ 5; Baran Decl. ¶ 24.)

Second, by lifting the cocking arm, the accused product is easily identified as discharged. (Haaga Decl., ¶ 6; Baran Decl. ¶ 29.) MDTech points to a small (3mm) window on the accused product that purportedly indicates whether the accused product is charged. (SJ Brief at 17, n. 4.) However, this window is not highly visible. In fact, MDTech’s expert, Dr. Rashidi, testified that when the cocking arm is closed, one could not tell whether the accused product was charged. (Auvil Decl. Ex. 7 (Rashidi Dep.) at 174:9-20.) The raised cocking arm is much more visible, and easily recognized as indicating a discharged state than the small window that MDTech’s own expert missed.

¹¹ Rashidi qualified this statement, noting that lifting the cranking arm at slow speed causes the needle to move too slowly to take a biopsy. *Id.* But in the situation described here—discharging a device outside of a patient for safety reasons—no tissue sample is being taken, so it is of no moment whether the needle moves fast enough to cut tissue.

MDTech argues that “visual proof that the instrument is not charged, can more easily and safely be obtained by firing the instrument properly using the Trigger Button and then lifting the handle [cocking arm] using only average force.” (SJ Brief at 17.) Even if this statement were true, it would not rescue the accused products from infringement. Because of potential damage to the needle that may occur from discharging the accused product outside of a patient, using the firing button in this manner is *less* safe. (Haaga Decl., ¶ 5; Auvil Decl. Ex. 6 (Haaga Dep.) at 200:2-14; Baran Decl., ¶ 23; *see also* Baran Decl. Ex. 13 (FDA Adverse Event Report 1046809.)) Further, the observation that pressing the firing button is easier than lifting the cocking arm does not render the lifting action improper. In fact, a reasonable operator could conclude that the effort of lifting the cocking arm is worth the safety benefit and that of eliminating potential needle damage. Moreover, even if MDTech’s argument was a cognizable defense, the qualitative evidence offered in support (discussions of “average force” or “above average force”) would be best weighed by the finder of fact.¹²

Finally, MDTech’s characterization of lifting the cocking arm as improper use does not square with the operator’s manual. Rather than warn against lifting the cocking arm, it defers to the physician, stating: “These instructions for the BioPince® Full Core Biopsy Instrument are NOT meant to define or suggest any medical or surgical technique.

¹² Moreover, MDTech’s statement in support of this argument are misleading. Although Dr. Haaga testified that “significant effort” was required to lift the blue cocking arm of the re-designed version of the accused products, he also stated that the original version (having a green cocking arm) was easy to lift (“the ease of doing this one is simple”). (Auvil Decl. Ex. 6 (Haaga Dep.) at 201-202.) Dr. Baran’s testimony also contradicts Sophie Marcoux’s declaration that the flat shelf of the blue cocking arm does impact functionality. (Dkt. No. 164-14, ¶ 3(b).) Contrary to Marcoux’s declaration (¶ 3(b)), the shelf in the green cocking arm is not merely angled, but is rounded. (*See* Baran Decl. ¶ 62, Fig. 14.) The flat shelf of the re-designed cocking arm does not flex the latch as easily as the rounded shelf. (Baran Decl. ¶ 64.) Therefore, the re-designed device is more difficult to open, as was demonstrated during the Haaga deposition. Notably, the cocking arm was redesigned in 2007, after MDTech was made aware of Dr. Baran’s infringement contentions. (*See* Marcoux Decl., ¶ 2.)

The individual physician is responsible for the proper procedure and techniques to be used with this product.” (Auvil Decl. Ex. 4 (BioPince Manual), MDT004145.)

In sum, and in view of the requirement of resolving doubts in Dr. Baran’s favor, MDTech’s arguments are insufficient to show an absence of a genuine issue of material fact with respect to the release means for retaining and, therefore, summary judgment as to this element should be denied.

V. CONCLUSION

MDTech’s summary judgment motion fails on many fronts. For example, it is predicated on a re-argument of claim construction for each disputed limitation, which is plainly improper. It also applies the wrong legal standard to the question of equivalents of the release means for retaining limitation. It further ignores evidence germane to Dr. Baran’s infringement theory (*e.g.*, that a patch of adhesive is a support) and, instead, sets up straw men arguments that Dr. Baran never made (*e.g.*, that a biopsy is performed by lifting the cocking arm 55). Finally, it fails to recognize genuine issues of material fact (*e.g.*, whether the accused product has an equivalent of the release means for retaining limitation) and that all doubts be resolved in Dr. Baran’s favor. For the foregoing reasons, Dr. Baran respectfully submits that MDTech’s motion should be denied.

Respectfully submitted,

DATED: February 12, 2009

/s/ Steven M. Auvil

Steven M. Auvil (0063827)

sauvil@beneschlaw.com

Bryan J. Jaketic (0078429)

bjaketic@beneschlaw.com

BENESCH, FRIEDLANDER,

COPLAN & ARONOFF LLP

200 Public Square, Suite 2300

Cleveland, Ohio 44114-2378

Telephone: (216) 363-4500

Facsimile: (216) 363-4588

Attorneys for Plaintiff

GREGORY W. BARAN, M.D.

CERTIFICATE OF SERVICE

I hereby certify that on February 12, 2009, a true copy of the foregoing **PLAINTIFF GREGORY W. BARAN, M.D.'S CORRECTED OPPOSITION TO DEFENDANT MEDICAL DEVICE TECHNOLOGIES, INC.'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Respectfully submitted,

DATED: February 12, 2009

/s/ Steven M. Auvil

One of the Attorneys for Plaintiff
GREGORY W. BARAN, M.D.